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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,062	01/03/2001	Zhongming Zeng	CCPIT102	9268

7590

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EXAMINER

TELLER, ROY R

12

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/674,062

Applicant(s)

ZENG, ZHONGMING

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-63 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of new claims 39-63 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that new claims 39-63 should not be subject to a restriction requirement/election of species. This is not found persuasive because a search of the amino acids would not necessarily include the pharmaceutical alkalis, anti-fungal drugs or plant extracts of the composition. In addition, a search for the invention of the amino acids would not be a complete and thorough search of the pertinent patent and non-patent technical literature. For example, the amino acids are differently searched and classified from the pharmaceutical alkalis, anti-fungal drugs and plant extracts.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-63 are pending and will be examined to the extent that they read on the elected invention of: group A- glutamic acid, group B- oligopeptide, group C- sodium bicarbonate, group D- Miconazole, and group E- Radix Sophorae Flavescentis. Amendment of the claims to delete non-elected subject matter is required prior to allowance.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1654

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49 and 56-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an oligopeptide, Miconazole and sodium bicarbonate, does not reasonably provide enablement for glutamic acid or an extract of *Radix Sophorae Flavescentis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977),

Art Unit: 1654

have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

*The nature of the invention:* The invention is drawn to a method of treating the abnormality of high acidity in the vagina, comprising administering a composition of one or more of : glutamic acid, an oligopeptide, sodium bicarbonate, Miconazole and Radix Sophorae Flavescentis.

*The state of the prior art and the predictability or lack thereof in the art:* Reinhard (USPN 5,573,765) teaches the use of Miconazole in the treatment of vaginal yeast infections, column 1, lines 21 and 44. Little (USPN 5,858,974) discloses the use of Miconazole and glutamic acid in the treatment of Candidiasis, column 1, line 56, column 4, line 22, and column 6, line 6.

*The amount of direction or guidance present and the presence or absence of working examples:* Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

Page 16, example 12 of the instant specification showed the mixing of Radix Sophorae Flavescentis in a lotion with various amino acids and vitamin C but does not teach therapeutic efficacy for an extract of Radix Sophorae Flavescentis used alone for treatment of fungal

Art Unit: 1654

vaginitis

Page 12, example 1 coupled with experimental example 1, page 19 of the instant specification showed the use of various amino acids, including glutamic acid, yeast extract powder, sodium bicarbonate and xanthan gum but does not teach therapeutic efficacy for glutamic acid used alone for treatment of fungal vaginitis.

*The breadth of the claims and the quantity of experimentation needed:* The quantity of experimentation required to enable the claims is considered undue. Prior art teaches the use of Miconazole and glutamic acid in the treatment of Candidiasis (Little, USPN 5,858,974). The instant specification teaches the use of an oligopeptide, sodium bicarbonate, and Miconazole in the treatment of fungal vaginitis. The specification does not teach the therapeutic efficacy of glutamic acid or an extract of Radix Sophorae Flavescentis used alone for treatment of fungal vaginitis

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 40, 50 and 52-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites "... **if necessary**..." , this is indefinite due to the lack of reference needed to determine what necessary encompasses. Claim 39 recites method steps which are unclear. Further, claim 39 recites "... **is adjust**..." which is not in the active form.

Art Unit: 1654

Claim 40 recites "...A **method**...", this is indefinite, because it does not refer to **the** method of claim 39.

Claims 50 and 52-63 are hybrid/composition method claims which are indefinite for failing to put forth active method steps.

Claims 41-49 and 51 are included in this rejection for depending upon a rejected claim.

***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT  
1654  
3/14/03

*Brenda Brumback*  
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